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Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Petition for Reconsideration and Stay of Action
Docket No. 98N-0583

The Grocery Manufacturers of America (GMA) and the Cosmetic, Toiletry, and Fragrance Association (CTFA) submit this petition in accordance with 21 C.F.R. 10.33(b) and 10.35(b) for reconsideration and stay of two provisions in the regulations promulgated by the Commissioner of Food and Drugs in Docket No. 98N-0583 (notification and recordkeeping requirements relating to export of food and cosmetics).

A. Decision Involved

FDA published proposed regulations to establish notification and recordkeeping requirements for export of products that may not be marketed or sold in the United States in 64 Fed. Reg. 15944 (April 2, 1999) and promulgated final regulations in 66 Fed. Reg. 65429 (December 19, 2001). The effective date for these regulations was extended until June 19, 2002, in 67 Fed. Reg. 34387 (May 4, 2002).

This petition for reconsideration and stay is directed only to the portion of these regulations that relate to the application to exported food and cosmetic products of Section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and only to two provisions in those regulations: (1) the last sentence in Section 1.101(b), which states that export records for a food or cosmetic shall be made available to FDA upon request during an inspection for review and copying, and (2) Section 1.101(b)(2), which places the burden on a food or cosmetic company to prepare a notarized certification by a responsible company official that an exported product does not conflict with the laws of the importing country.

B. Action Requested

Petitioners request the Commissioner to reconsider and to revoke the last sentence in Section 1.101(b) and to revoke Section 1.101(b)(2). Petitioners also request that these two provisions be stayed during this reconsideration.

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C. Statement of Grounds

This petition addresses two separate and different provisions of the export regulations. Each of these provisions is described separately below and discussed in detail in the attached two appendices.

1. Records Inspection

For a full fifty years, FDA has taken the consistent position that the FD&C Act does not authorize the Agency to require a food or cosmetic company to disclose records to the Agency relating to these products. Congress has authorized records inspection for a limited category of products (prescription drugs, restricted medical devices, infant formula, and nonprescription drugs) but has repeatedly declined to extend records inspection authority to cover food generally or cosmetics.

FDA acknowledged this lack of authority in a press release issued by the Agency at the time of the enactment of the inspection provisions in Section 704 of the Act in 1953. FDA officials have repeatedly testified before Congress that the Agency lacks records inspection authority for food and cosmetics from 1962 to the present. None of this history is discussed in the preamble to the proposed or final regulations, and these preambles provide no explanation for the present assertion of this authority. A full discussion of all of these points is set forth in Appendix A to this petition.

Accordingly, petitioners request that the last sentence of the first paragraph in Section 1.101(b) of the export regulations, as promulgated in 66 Fed. Reg. 65429, 65447 (December 19, 2001), be revoked.

2. Compliance With Foreign Law

Under the export provision in the Federal Food and Drugs Act of 1906, which required compliance with foreign law, FDA promulgated implementing regulations that explicitly acknowledged that FDA, rather than the regulated industry, had the burden of proving lack of compliance with foreign law. The courts interpreted the export provision in the 1906 Act in the same way.

The export provision in the legislation that ultimately became Section 801(e)(1)(B) of the FD&C Act was initially drafted by FDA to reverse the burden of proof, and thus to require the regulated industry to demonstrate compliance with foreign law. When this was brought to the attention of Congress, the pending legislation was changed in 1937 specifically to retain the burden of proof on FDA. The legislative history demonstrates that Congress intended the export provision under the 1938 Act to remain the same as the export provision under the 1906 Act. None of this legislative history is discussed in the preamble to the proposed or final regulations. A full discussion of all of these points is set forth in Appendix B to this petition.

In addition to the illegality of Section 1.101(b)(2) of the export regulations, this provision would have serious practical and economic impacts on food and cosmetic companies. It is common practice for companies who export products to label them in the United States in foreign languages, before export, in order to meet foreign requirements throughout the world. For sixty-four years they have done this under Section 801(e)(1)(B) of the FD&C Act without the need for special documentation of the type that would now be required under Section 1.101(b)(2). The new provision would require the preparation of tens of thousands of affidavits just for shipping products to our neighbors in Mexico (Spanish labeling) and Canada (dual French and English labeling), and new affidavits would be required for every product variation and every label change. FDA has presented no evidence that the approach used for the last sixty-four years has in any significant way harmed foreign consumers or relations between the United States and our trading partners.

Accordingly, petitioners request that Section 1.101(b)(2), as promulgated in 66 Fed. Reg. 65429, 65447 (December 19, 2001), be revoked.

3. Timeliness of Petition

Sections 10.33(b) and 10.35(b) of the FDA procedural regulations state that a petition for administrative reconsideration or for stay of action is ordinarily to be filed within thirty days after the date that a regulation is published in the Federal Register. Both provisions state, however, that a petition may be accepted by the Commissioner at a later date for good cause.

In this matter, the petitioners did not recognize the significance of the two provisions that are the subject of this petition until the effective date of the regulations drew near. Following the extension of the effective date, petitioners concluded that it would be appropriate to submit this petition for a further stay of action in order to provide time for reconsideration of these two matters. Because of the importance of these matters, petitioners request the Commissioner to exercise the discretion set forth in the applicable regulations to reconsider these matters and to stay their effective date until that reconsideration can be completed.

Respectfully submitted,

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